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510(k) Summary
NEOORTHO Produtos Ortopédicos S/A
Small and Large Fragments Osteosynthesis System NEOFIX
K113733

February 22, 2012

ADMINISTRATIVE INFORMATION

Manufacturer Name:	NEOORTHO Produtos Ortopédicos S/A Rua Ângelo Domingos Durigan 607, Cascatinha 82020-340 Curitiba - PR, Brazil Telephone: +55 41 3535-1033 Fax: +55 41 3535-1018
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Small and Large Fragments Osteosynthesis System NEOFIX
Common Names:	Plate, fixation, bone Screw, fixation, bone
Classification Names:	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Classification Regulations:	21 CFR 888.3030, Class II 21 CFR 888.3040, Class II
Product Codes:	HRS HWC
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

Small and Large Fragments Osteosynthesis System NEOFIX is intended for small and large bone fracture fixation, arthrodesis and osteotomy fixation. Examples include: fractures of the clavicle, scapula, humerus, olecranon, radius, ulna, carpals, metacarpals, distal femur, proximal tibia, tibial pilon, fibula, calcaneus, tarsals and metatarsals; small fragments of the hand and wrist; pelvis and acetabulum fractures; periprosthetic fractures; metatarsal and phalangeal osteotomies; and carpal, metacarpal, wrist and ankle arthrodesis. The use of locking plate/screw systems is suited for treatment of fractures in osteopenic bone. This system is not indicated for use in the spine.

DEVICE DESCRIPTION

NEOFIX consists of plates and screws in a variety of designs and sizes and made from commercially pure titanium or Ti-6Al-4V alloy. Plates are provided in straight designs and in various geometric configurations that are commonly used in trauma and reconstructive surgery. Plates are provided with screw holes to accommodate non-locking and locking screws designs. Screws are provided in cortical (locking and non-locking) and cancellous thread designs in various diameters and lengths.

EQUIVALENCE TO MARKETED DEVICE

NEOORTHO Produtos Ortopédicos S/A demonstrated that, for the purposes of FDA's regulation of medical devices, Small and Large Fragments Osteosynthesis System NEOFIX is substantially equivalent in indications and design principles to the following predicate devices.

Predicate Number	K Number	Company Name	Device Name
1	K012655	Acumed, Inc.	Congruent Bone Plate System
2	K071715	Acumed, Inc	Acumed Congruent Bone Plate System
3	K041860	Synthes (USA)	Synthes (USA) LCP® Proximal Humerus Plates, long
4	K011815	Synthes (USA)	Synthes LCP Proximal Humerus Plates
5	K101421	DePuy Orthopaedics, Inc	DePuy Anatomic Locked Plating System Long Plate Line Extension
6	K000684	Synthes (USA)	Synthes (USA) Small Fragment Dynamic Compression Locking (DCL) System
7	K011335	Synthes (USA)	Synthes One-Third Tubular Plate
8	K000558	Synthes (USA)	Synthes (USA) Wrist Fusion Plates (WFP)
9	K020401	Synthes (USA),	Synthes Calcaneal Plate
10	K020602	Synthes (USA)	Synthes Pilon Plate
11	K023802	Synthes (USA)	Synthes (USA) 4.5 mm Titanium LCP Proximal Tibia Plating System
12	K092609	Synthes (USA)	Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP)
13	K010766	Synthes (USA)	Synthes (USA) Large Fragment Locking Compression Plate (LCP) System-T Plate
14	K081353	Synthes (USA)	Synthes (USA) TomoFix™ Medial Distal Femur Plates

Predicate Number	K Number	Company Name	Device Name
15	K023941	Synthes (USA)	Synthes (USA) TomoFix™ Osteotomy System
16	K000089	Synthes (USA)	Synthes 4.0 and 5.0 mm Locking Screws
17	K041533	Synthes (USA)	Peri-Prosthetic Screws
18	K033995	Synthes (USA)	Synthes (USA) 3.5 mm LCP Distal Humerus System
19	K043185	Synthes (USA)	Synthes (USA) 3.5 mm Cortex Screws
20	K961413	Synthes (USA)	Synthes Anatomical Locking Plate System
21	K061621	Synthes (USA)	Synthes (USA) 6.5 mm Cancellous Screws
22	K031573	Synthes (USA)	Synthes 3.5 mm Low Profile Pelvic Reconstruction Plate

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject and predicate devices are all fabricated from the same or similar materials and share similar design characteristics. The subject and predicate devices encompass the same range of physical dimensions, are packaged using the same materials, and are to be sterilized by the same methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy.

Performance data provided to demonstrate substantial equivalence included engineering analysis and mechanical testing according to ASTM F382 and ASTM F543.

Overall, Small and Large Fragments Osteosynthesis System NEOFIX has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NEOOTHO Produtos Orthopédicos S/A
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San Diego, California 92130

MAR 2 3 2012

Re: K113733
Trade/Device Name: Internal Fixation System NEOFIX
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: March 9, 2012
Received: March 12, 2012

Dear Dr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K113733

Device Name: Internal Fixation System NEOFIX

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113733